

**Notice of Allowability**

Application No.

10/067,146

Examiner

Sumesh Kaushal Ph.D.

Applicant(s)

SIEGAL ET AL.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/18/05.
2. ☒ The allowed claim(s) is/are 11,15,21-24,26-30 and 32-35.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Elie H. Gendloff on 02/13/06.

The application has been amended as follows:

### IN THE CLAIMS

Claim 36 has been canceled.

In claim 11, line 7, "an" has been replaced with -- a -- before "appropriate control" and in line 11 "may be" has been replaced with -- is -- before "progressing".

In claim 15 line 7, "may be" has been replaced with -- is -- before "effective".

In claim 21, line 1, "lymphoid tissue or" is deleted before "blood sample".

In claim 26, line 1, "lymphoid tissue or" is deleted before "blood sample".

In claim 30, line 7, "an" has been replaced with -- a -- before "appropriate control" and in line 10, "may not be" has been replaced with -- is not -- before "progressing".

In claim 32, line 1, "lymphoid tissue or" is deleted before "blood sample".

### IN THE SPECIFICATION

Page 3, line 20, -- (B) -- was inserted before "The isotope controls".

### REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: Claims 11, 15, 21-24, 26-30 and 32-35 are free of prior art of record. The prior art does not teach or suggest a method of assessing the effectiveness of a therapeutic composition or monitoring HIV infection or AIDS in patient by enumerating the number of pDC2 dendritic cells (CD4<sup>+</sup>, CD3<sup>-</sup> and CD11c<sup>-</sup>) in HIV infection or AIDS in patient.

The art made of record and not relied upon is considered pertinent to applicant's disclosure.


- Schmidt B, Fujimura SH, Martin JN, Levy JA. Variations in Plasmacytoid Dendritic Cell (PDC) and Myeloid Dendritic Cell (MDC) Levels in HIV-Infected Subjects on and off Antiretroviral Therapy. J Clin Immunol. 26(1):55-64, 2006.
- Finke JS, Shodell M, Shah K, Siegal FP, Steinman RM. Dendritic cell numbers in the blood of HIV-1 infected patients before and after changes in antiretroviral therapy. J Clin Immunol. 24(6):647-52, 2004.
- Siegal FP, Kadowaki N, Shodell M, Fitzgerald-Bocarsly PA, Shah K, Ho S, Antonenko S, Liu YJ. The nature of the principal type 1 interferon-producing cells in human blood. Science. 284(5421):1835-7, 1999 (ref. of record).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to **571-272-0547**. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**

  
**SUMESH KAUSHAL**  
**PRIMARY EXAMINER**  
**ART UNIT 1633**